

**AMENDMENTS TO THE SPECIFICATION**

Please amend the paragraph beginning on page 1, line 8, as follows:

This application is a continuation of U.S. Application Serial No. 10/212,897, filed August 5, 2003 which is a continuation of U.S. Application Serial No. 09/975,085, filed October 9, 2001 (now issued U.S. Patent 6,431,167, issued October 9, 2001), which is a continuation of U.S. Application Serial No. 09/888,094, filed June 21, 2001 (now issued U.S. Patent 6,427,681, issued June 21, 2001), which is a continuation of U.S. Application Serial No. 09/656,535 filed September 7, 2000 (now U.S. Patent 6,250,298 issued June 26, 2001) which is a divisional of U.S. Application Serial No. 09/004,756 filed January 8, 1998 (now U.S. Patent 6,131,567 issued October 17, 2000), which is a continuation-in-part of U.S. Application Serial No. 08/792,616 filed January 31, 1997 (now U.S. Patent 5,888,477 issued March 30, 1999) which is a continuation-in-part of application Serial No. 08/754,423, filed November 22, 1996 (now U.S. Patent 5,473,250 issued April 28, 1998), which is a continuation-in-part of application Serial No. 08/549,343, filed October 27, 1995 (now issued U.S. Patent 5,915,378, issued June 29, 1999), which is a continuation-in-part of application Serial No. 08/331,056, filed October 28, 1994 (now U.S. Patent 5,672,581 issued September 30, 1997), which is a continuation-in-part of application Serial No. 08/011,281, filed January 29, 1993 (now U.S. Patent 5,364,838 issued November 15, 1994) all of which are incorporated ~~which application is incorporation~~ herein by reference and to which application we claim priority under 35 U.S.C. §120--.

Please delete the paragraph beginning on page 8, line 15 and replace it with the following paragraph:

It is an object of this invention to demonstrate that aerosolized delivery of Humalog<sup>TM</sup> in place of conventional formulations of recombinant human insulin makes a repeatable blood concentration *versus* time profile substantially less dependent of on the patients final inhaled volume at delivery.

Please delete the paragraph beginning on page 12, line 4 and replace it with the following paragraph:

The term "blood concentration *versus* time profile" shall be interpreted to mean the concentration of a drug in the blood or plasma over time. This can be characterized by means of a graph

showing the concentration of a drug (e.g. insulin or an insulin analog or “immunoreactive insulin” as a surrogate measurement for an insulin analog such as insulin lispro) on the Y axis and time on the X axis. The blood concentration *versus* time profile can also be characterized by certain pharmacokinetic parameters such as  $C_{\max}$  (the maximum concentration of the drug seen over the measured time interval) and  $T_{\max}$  (the time at which  $C_{\max}$  was observed). Note that, by these criteria, two different blood concentration *versus* time profiles may be associated with similar or even identical bioavailability measurements. The blood concentration *versus* time profile is crucial for drugs such as insulin and insulin analogs where the time at which peak concentration preferably occurs in ~~conjunction with peak~~ relation to the using blood glucose levels following a meal. Different values of  $T_{\max}$  for two different insulin preparations or delivery methods could therefore be associated with significant differences in safety and efficacy.

Please delete the paragraph beginning on page 14, line 5 and replace it with the following paragraph:

The term "formulation" is used to encompass the term "liquid formulation" and to further include dry powders of insulin and/or ~~monomer~~ monomeric insulin along with excipient materials. Preferred formulations are aqueous solutions of monomeric insulin but include dry powders and dispersions.

Please delete the paragraph beginning on page 17, line 2 and replace it with the following paragraph:

A comparison of Figures 1 and 2 as well as tables 1 and 2 shows that inhaling to a low or high volume at delivery does not effect the results significantly ~~results~~ when delivery monomeric insulin -- but substantially effects the results when delivering insulin